December 10, 2021

LG Electronics Inc.
% Bokyeong Kim
Senior Researcher
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
REPUBLIC OF KOREA

Re: K212137
Trade/Device Name: ASHK100G
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 5, 2021
Received: November 8, 2021

Dear Bokyeong Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212137

Device Name
ASHK100G

Indications for Use *(Describe)*
Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K212137

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39381, Republic of Korea
Tel: +82-1544-7777

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

July 2, 2021

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: LG Electronics
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Republic of Korea, 3938
- Contact Name: Jinhwan Jun / Chief Research Engineer
  - Telephone No.: +82-31-8066-5641
  - Email Address: jinhwan.jun@lge.com
- Name of Manufacturer: LG Electronics
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Republic of Korea, 3938

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Product Name	LG Acquisition Workstation Software
Model Name	ASHK100G
Trade Name	X-Clever
Device Classification Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Product Code Name	System, Image Processing, Radiological
Device Class	II
510k Review Panel	Radiology

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate Device

- 510(k) Number: K191188
- Applicant: LG Electronics
- Trade/Device Name: ASHK100G
- Regulation Name: Picture archiving and communications system
- Regulation Number: 21 CFR 892.2050
- Classification Product Code: LLZ
- Device Class: II
- 510(k) Review Panel: Radiology

The predicate device has not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

LG Acquisition Workstation Software ASHK100G is a diagnostic software for final post-processed X-ray images of body parts of actual patients acquired through the integration of digital X-ray detectors (DXDs) and X-ray generators. By integrating the [MWL] and the [PACS] server, this software can be used to check the information and images of the patients' body parts in real time in an HIS (Hospital Information System) based environment.

A new image post-processing algorithm, MLP3 has been added to the proposed device. MLP3 provides image quality that is substantially equivalent to or slightly better than the predicate device even at lower x-ray dose levels. In addition, the functions have been added or modified to improve the user interface.

6. Indications for Use [21 CFR 807.92(a)(5)]

Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)

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7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

ASHK100G is medical software. It digitalizes the signal sent from the detector and displays the x-ray image. Also, it can enter patient information, shot information, and other necessary references for convenience.

Compared with the predicate device ASHK100G (Ver 1.00), the technological characteristics of the proposed device, ASHK100G (Ver 3.01.XX), are substantially equivalent to those of the predicate device. The proposed device is functionally similar to the predicate device. The table below presents comparisons for each device:

[Table. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device	Note
K Number	Not known	K191188	-
Manufacturer	LG Electronics	LG Electronics	Same
Model name	ASHK100G	ASHK100G	Same
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)	Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)	Same
SW Version	3.01.XX	1.00	Modified
Processor	Intel 6th gen i5	Intel® Core i5 or higher	Same
RAM	8GB or higher	8GB or higher	Same
Hard Disk	512 GB or greater recommended	min. 500GByte	Same
Network	Dual Ethernet 100/1000Mbps	100MBit or 1GBit	Same

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	Proposed Device	Predicate Device	Note	
Operation Software	Microsoft Windows 8.1(64 bit) Microsoft Windows 10(64 bit)	Microsoft Windows 7(64 bit) Microsoft Windows 8.1(64 bit) Microsoft Windows 10(64 bit)	Modified	OS recommended specifications change for better program compatibility and image processing performance
Resolution	1920 x 1080, 3840 x 2160	min. 1920 x 1080	Modified	Available resolutions specified for full compatibility (Program doesn't support the not FHD and not UHD case fully)
Generator Control protocol	Yes	Yes	Same	
Image Processing	Yes - MLP2 image processing algorithm - MLP3 image processing algorithm	Yes - MLP2 image processing algorithm	Modified	Improves image quality even at lower x-ray doses (The proposed device also supports MLP2 for existing users.) If [Apply MLP3] option in 'Advanced processing' menu is selected, the MLP3 algorithm is applied.
Windowing	Yes	Yes	Same	
Image formatting	Yes (1x1,1x2,2x2,3x3)	Yes (1x1,2x2,3x3,4x4)	Modified	Modified for more used layout types
Body map function	Yes	No	Modified	Modified for adding a patient study easily
Exposure index function	Yes	No	Modified	For displaying how much x-ray radiation exposed compared to target value
Scale function	Yes	No	Modified	To measure object size roughly without any tool usage in viewer (Specific site requirements)
SW Grid	Yes	No	Modified	Improves the image quality of a chest x-ray image acquired without an anti-scatter grid.
Visual grid function	Yes	No	Modified	Like scale function, it measures object size

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39381, Republic of Korea
Tel: +82-1544-7777

	Proposed Device	Predicate Device	Note	
				roughly without any tool usage in viewer User can check object active area in grid pattern
Worklist merge	Yes	No	Modified	In case of a patient with multiple studies, user can check all studies in exam menu just one entry
Auto ROI size	Yes	No	Modified	Added to use default shutter ROI area on each body part for better usage
Electronic zoom	Yes	Yes	Same	
Image rotation	Yes	Yes	Same	
Image annotation	Yes	Yes	Same	
Image Stitch	Yes	Yes	Same	
DICOM Worklist	Yes	Yes	Same	
DICOM Store	Yes	Yes	Same	
DICOM Print	Yes	Yes	Same	

The predicate device is a previous version of the proposed device. The modified (improved) items from predicate device are described in above table. The main change point is the addition of MLP3, a new image post-processing algorithm, and other changes to improve the Use interface. MLP3 algorithm is upgraded with employing noise reduction algorithm and scatter correction algorithm for improvement of image quality. MLP3 noise reduction algorithm predicts noise present in low dose images and adaptively reduces the noise, by which image quality is improved. And, MLP3 scatter correction algorithm predicts scattered x-ray present in images acquired without an anti-scatter grid and adaptively reduces the scattered radiation, by which image quality is improved.

There are no significant differences between subject device and the predicate device that would adversely affect the use of the product. The proposed device has been tested clinically for the new post processing algorithm and software has been validated.

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8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The ASHK100G is MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005

- Software Validation
- Compatibility with Generator Test
- Measuring Function Verification
- Software Function Test
- Performance for Stitch Feature
- Exposure Index

2) Cybersecurity

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, on October2, 2014

3) Performance Test

- MLP3 post processing algorithm

  To prove that our proposed device is suitable for imaging adult and pediatric body parts, we have provided bench testing results, as follows, for general imaging characteristics of our new device in comparison with our predicate device:

  - In house image quality evaluation for adults

  : For adults, we provided an image quality comparison report. Clinical images of 30 common radiographic positions, recommended by FDA's guidance for digital x-ray detectors, are presented. Clinical images were post-processed with our new (MLP3) and old (MLP2) image processing algorithms separately, and their image quality were evaluated. The results show that our new image processing algorithm provides image quality equivalent to or slightly better than the predicate device.

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- In house image quality evaluation for pediatric and infant

: For pediatric and infant imaging, we provided phantom testing results for a range of exams including chest, skull, abdomen and pelvis. These phantom images were post-processed with our new (MLP3) and old (MLP2) image processing algorithms separately, and their image quality were evaluated. The results show that our new image processing algorithm provides image quality equivalent to or slightly better than the predicate device.

9. Clinical Test Summary [21 CFR 807.92(b)(2)]

The proposed device (ASHK100G, ver 3.01.XX) includes new image processing algorithm (MLP3), which improves the image quality of x-ray images acquired at standard and low radiation doses. The new MLP3 algorithm provides image quality that is substantially equivalent to or slightly better than the predicate device (ASHK100G, ver 1.00) even at lower x-ray doses.

The new MLP3 algorithm incorporates two sub-algorithms:

(1) MLP3 noise reduction algorithm predicts noise present in low dose images and adaptively reduces the noise, by which image quality is improved. The image quality of the low dose image is enhanced and becomes comparable to that of an image taken at standard x-ray dose level.

A clinical study was conducted to support our marketing claims. From one small clinical study performed at one clinical site, images were acquired from one stationary x-ray system with a fixed tube voltage of 120 kVp and dose levels were adjusted by varying the exposure time with other imaging parameters (mA, distance, grid) kept constant. Clinical images acquired from forty patients were evaluated by three board certified radiologists. The study showed that the image quality of adult chest PA x-rays taken at lower radiation doses and processed with our new image processing algorithm improved the overall diagnostic image quality, which became substantially equivalent to that of x-ray images acquired at standard dose levels. On average, radiation dose of images acquired at lower doses were approximately 50% less than that of images acquired at standard doses.

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(2) MLP3 scatter correction algorithm predicts scattered x-ray present in images acquired without an anti-scatter grid and adaptively reduces the scattered radiation, by which image quality is improved. The resulting image quality of the non-grid image is enhanced and becomes comparable to that of an image taken with an anti-scatter grid.

A clinical study was conducted to support our marketing claims. From one small clinical study performed at one clinical site, images were acquired from one mobile x-ray system with and without using an anti-scatter grid. Clinical images acquired from forty patients were evaluated by two board certified radiologists. The study showed that with our new algorithm, the image quality is improved for adult chest AP x-rays taken without an anti-scatter grid, and the improved image quality becomes comparable to images taken with an anti-scatter grid. On average, the radiation dose of non-grid images were 37% lower than that of grid images.

10.Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between proposed device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics. ASHK100G ver 3.01.XX is improved and added the functions compared to ASHK100G ver 1.00. The SW Validation, hazard analysis, risk control and performance test were conducted for the software features which are added or changed from ASHK100G (ver 1.00), the previous version.

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11.Conclusion [21 CFR 807.92(b)(3)]

There are no significant differences between the ASHK100G and the predicate device(s) that would adversely affect the use of the product. The updated ASHK100G version 3.01.XX is as safe and effective as the predicate version previously cleared in K191188. The subject device has the same intended use and similar technological characteristics, with differences supported by performance validation testing demonstrating that the subject device is safe and effective as the predicate device. Thus, the technological differences between ASHK100G version 3.01.XX and its predicate device raise no new issues of safety or effectiveness, and the updated ASHK100G version 3.01.XX is substantially equivalent.